UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,396	03/31/2004	Benjamin D. McDaniel	51992/AW/W112	9596

23363 7590 04/19/2010
CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

MAIL DATE	DELIVERY MODE
04/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,396	MCDANIEL ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,11-15,17-22 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,11-15,17-22 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and comments, received February 22, 2010, have been fully considered by the examiner. The following is a complete response to the February 22, 2010 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-4, 7, 13, 17-22 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. (U.S. Pat. No. 6,117,101) in view of the teachings of Collins et al (6,837,886) and Abele (U.S. Pat. No. 5,860,974).

Regarding claim 1, Diederich et al. disclose a catheter comprising: an elongated catheter body 652 having proximal and distal ends and at least one lumen therethrough (Fig. 13); a three-dimensional ablation assembly 650 at or near the distal end of the catheter body, said assembly having a framework 651 defining a length and a circumference, the assembly movable into a collapsed configuration with a greater length and a lesser circumference and an expanded configuration with a lesser length and a greater circumference, the framework comprising a plurality of tensile members interwoven in a manner such that the length increases as the circumference decreases and vice versa (col. 26, In. 38-44 and Fig. 13); said assembly also having a ribbon electrode extending along said circumference, said ribbon electrode adapted to move with said framework (col. 27, In.12-25).

Diederich et al fail to expressly state that the expanded assembly has a shape that changes to conform to non-uniformly shaped tubular regions. While the examiner maintains that the small wires of the Diederich et al expansion member would inherently be capable of such a function, attention is nonetheless directed towards the Collins et al reference which specifically teaches it is known to provide such an expandable member with this property. Specifically, Collins et al teach an analogous device that includes a braided, expandable member (28) for expanding into contact with tissue just as with Diederich. Collins et al specifically disclose that the expandable device is conformable to variations found in specific sites (col. 10, lines 56-60). Collins et al also teach the device may alternatively be made "stronger" to force tissue to conform to the device (col. 10, lines 60-64). Hence, Collins et al teach that it is known to make such an expandable member either conformable to tissue, or strong enough to conform tissue as desired.

Diederich et al also fail to disclose a tip electrode. Abele, as addressed in the previous Office action, teaches that it is obvious to use an analogous expandable cage electrode to ablate a heart chamber wall in order to correct arrhythmias (col. 1, In. 12-15 and Figs. 24-25). Abele further teaches that it is advantageous to have a tip electrode mounted at a distal end 76 of such an ablation assembly 72 in order to sense cardiac signals to locate the target tissue to be ablated and/or to provide an additional ablation electrode (col. 7, In. 35-45, col. 8, In. 7-8, 58-64, and Figs. 13, 17, and 18).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have mounted a tip electrode at the distal end of the

ablation assembly of Diederich in view of the teaching of Abele in order to sense cardiac signals to locate the target tissue to be ablated and/or to provide an additional ablation electrode. It would have been further obvious to the skilled artisan to have provided the Diederich device with a conformable expandable member to conform to non-uniform tissue since Collins et al fairly teach that such a construction is known in an analogous device.

Regarding claim 2, Diederich further discloses that said framework of the assembly in the expanded configuration has a first circumference in a first section along its length and a different second circumference in a second section along its length (col. 26, In. 38-44 and Fig. 13).

Regarding claim 3, Diederich further discloses an expander 653 attached at or near its end to distal ends of the tensile members 651 (col. 26, In. 34-44 and Fig. 13) and extending through the catheter body (col. 26, In. 26-35), the expander having a proximal end that extends out the proximal end of the catheter and having a lumen extending therethrough (col. 26, In. 34-44 and Fig. 13), whereby, in use, the expander can be moved longitudinally relative to the catheter body 652 to expand and collapse the ablation assembly. Since the expander 653 is used to expand the ablation assembly, it must inherently have a proximal end that extends out the proximal end of the catheter body so that the user can actuate it.

Regarding claim 4, Diederich further discloses that the expander 653 extends through at least a distal portion of the catheter body 652 (col. 26, In. 26-44 and Fig. 13). In addition, see the preceding rejection of claim 3.

Regarding claim 7, Diederich further discloses that the expander is moved proximally to actuate the assembly into the expanded configuration (Fig. 13).

Regarding claim 13, Diederich further discloses that the expander has a proximal end attached to a control handle. Since the expander is used to actuate the assembly expansion, the expander must inherently have a control handle to allow the user to actuate the expander.

Regarding claim 17, Diederich further discloses that the expander 653 is generally coaxial with the catheter body 652 (Fig. 13).

Regarding claim 18, Diederich further discloses that the expander 653 forms the axis of the assembly 650 (Fig. 13).

Regarding claim 19, Diederich further discloses that the assembly 650 comprises at least four tensile members 651 (Fig. 13).

Regarding claim 20, Diederich further discloses that each tensile member 651 comprises an internal flexible wire and a non-conductive covering over the flexible wire (col. 27, In. 5-6 and Fig. 13).

Regarding claim 21, Collins et al provides the additional teaching of making the flexible wire from NITINOL (col. 5, line 61-62).

Regarding claim 22, Diederich further discloses that the ribbon electrode is elastic (col. 27, In. 12-25).

Regarding claim 31, the claim differs from Diederich in calling for a plurality of ribbon electrodes. It would have been obvious, however, to one of ordinary skill in the art at the time the invention was made to provide a plurality of ribbon electrodes, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8. Further, Abele teaches a plurality of ribbon electrodes 40, 42 on an analogous expandable member in order to allow bipolar ablation (col. 3, In. 29-32, col. 6, In. 49-54 and Figs. 4-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ribbon electrodes in the device of Diederich in view of the teaching of Abele in order to allow bipolar ablation.

Regarding claims 32, 33 and 35, Collins et al provides the teaching of making the expandable ablation member from a material that conforms to non-uniform tissue as addressed with regard to the rejection of claim 1 above.

Claims 11-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. ('101) in view of Collins et al ('886) and Abele ('974), and further in view of Webster, Jr. (U.S. Pat. No. 5,772,590).

Regarding claim 11, Diederich discloses that the expander comprises a tube (col. 26, In. 34-36). The claim differs from Diederich et al. in calling for the expander to

comprise plastic tubing. Webster, Jr., however, teaches an expandable electrode catheter with an expander 56 comprising plastic tubing (col. 9, In. 12-13 and Fig. 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the expander of Diederich et al. comprise plastic tubing in view of the teaching of Webster, Jr. because plastic is an obvious alternate material for constructing tubes that is well-known in the art.

Regarding claim 12, Diederich discloses that the expander comprises a tube (col. 26, In. 34-36). The claim differs from Diederich et al. in calling for the expander to comprise braided plastic tubing. Webster, Jr., however, teaches an expandable electrode catheter with tube 7 comprising braided plastic tubing (col. 5, In. 13-16 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the expander of Diederich et al. comprise braided plastic tubing in view of the teaching of Webster, Jr. because braided plastic is an obvious alternate material for constructing tubes that is generally known in the art (pg. 14 of applicant's specification).

Regarding claim 14, the claim differs from Diederich et al. in calling for the control handle to comprise: a handle housing having proximal and distal ends, and a piston having a proximal end mounted in the distal end of the handle housing and a distal end fixedly attached to the proximal end of the catheter body; wherein the proximal end of the expander is fixedly attached, directly or indirectly, to the handle housing so that longitudinal movement of the piston relative to the handle housing results in longitudinal

movement of the expander relative to the catheter body to thereby expand and collapse the assembly.

Webster, Jr. ('590), however, teaches an expandable electrode catheter with a control handle 50 (Fig. 9) comprising the handle of U.S. Pat. No. 4,960,134 also to Webster, Jr. (incorporated by reference into Webster, Jr. '590).

With reference to Webster, Jr. ('134), the control handle 13 comprises:
a handle housing 40 having proximal and distal ends, and a piston 46 having a proximal end mounted in the distal end of the handle housing and a distal end fixedly attached to the proximal end of the catheter body 11 (col. 4, In. 45-49 and Fig. 4);

With reference to Webster, Jr. ('590), the control handle 50 comprises an expander 54, wherein the proximal end of the expander is fixedly attached, directly or indirectly, to the handle housing so that longitudinal movement of the piston relative to the handle housing results in longitudinal movement of the expander relative to the catheter body to thereby expand and collapse the assembly (col. 8, In. 61 - col. 9, In. 7 and Figs. 9-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the control handle of Diederich et al. to comprise the control handle of Webster, Jr. ('590/'134) in view of Webster, Jr. ('590) as an obvious way to expand the tensile members of Diederich et al. that is known in the art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Collins et al 9'886) and Abele ('974) and Webster, Jr. ('590) as addressed above, and further in view of Edwards et al. (U.S. Pat. No. 5,471,982) and Webster, Jr. (U.S. Pat. No. 6,183,463 B1).

Regarding claim 15, the claim differs from Diederich et al. in calling for the proximal end of the expander to extend outside the proximal end of the control handle and through a support tube.

Edwards et al. teach an expandable electrode catheter, wherein fluid is introduced to the point of ablation through the expander tube 240 to keep the electrodes free of tissue buildup and blood (col. 19, In. 50 - col. 20, In. 2 and Figs. 12 and 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included fluid introduction through the expander tube of Diederich et al. in view of the teaching of Edwards et al. to keep the electrodes free of tissue buildup and blood.

Webster, Jr. ('463)teaches an electrode catheter, comprising the piston control handle of Webster, Jr. ('590/'134) with a fluid introduction tube 88 that starts at the distal electrode end and then extends outside the proximal end of the control handle and through a support tube 91 (col. 8, In. 18-26, col. 9, In. 7-26, and Figs. 1-4). Fluid is introduced through the luer hub 90 (col. 8, In. 33-39 and Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the proximal end of the expander/fluid introduction

tube of Diederich et al. in view of Edwards et al. to extend outside the proximal end of the control handle of Diederich et al. in view of Webster, Jr. ('590/'134) and through a support tube further in view of the teaching of Webster, Jr. ('463) as an obvious alternate way of introducing fluid that is known in the art for use with the control handle of Webster, Jr. ('590/'134).

Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. ('101) in view of Collins et al ('886) and Abele ('974), and further in view of the teaching of Maguire et al (6,514,249).

The claim differs from Diederich in calling for proximal and distal location sensors, and a tip electrode mounted at or near a distal end of the ablation assembly.

Maguire et al, as addressed in the previous Office action, disclose substantially the same device as Diederich et al, and also include a similar embodiment having an expandable framework ablation element (Figure 17a). In particular, Maguire et al specifically teach that it is known to provide location sensors (516,518 – Figure 5C) proximal and distal to an ablation device to assist in locating the ablation element at a desired location.

To have provided the Diederich et al device, as modified by the teachings of Collins et al and Abele et al, with sensing electrodes to assist is locating the ablation element at a desired tissue site would have been an obvious design modification for one

of ordinary skill in the art since Maguire et al fairly teach it is known to use such sensors in an analogous device.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. ('101) in view of Collins et al ('886).

The Diederich et al device as modified by the Collins et al teaching has been fully addressed with respect to claim 1 above. Claim 38 fails to recite a tip electrode as required in independent claim 1. Hence, the limitations of claim 1, and the application of the Diederich et al and the Collins et al references, are substantially identical to the limitations of claim 38 with the exception of the tip electrode.

To have provided the Diederich et al expandable member with a construction to allow conformance of the ablation member to non-uniform tissue to assure complete ablation would have been an obvious design consideration for one of ordinary skill in the art since Collins et al fairly teach it is known to provide such a design for an expandable ablation member in an analogous device.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

The examiner has supplied the Collins et al reference to address the newly added limitation of an expandable member that, when expanded, has a variable shape to conform to non-uniform tissues. As asserted above, Collins et al teach an analogous

expandable ablation device that may having either a conforming or a non-conforming construction as desired.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
April 14, 2010